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UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF OKLAHOMA

IN RE: GENENTECH HERCEPTIN)
(TRASTUZUMAB) MARKETING AND) Case No. 16-MD-2700-TCK-TLW
SALES PRACTICES LITIGATION.) ALL CASES

TRANSCRIPT OF RECORDED PROCEEDINGS
AUGUST 26, 2016
BEFORE THE HONORABLE T. LANE WILSON, MAGISTRATE JUDGE PRESIDING
DISCOVERY CONFERENCE

Greg Bloxom, RMR, CRR
United States Court Reporter
Northern District of Oklahoma

A P P E A R A N C E S

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1 PROCEEDINGS:

2 -----

3 **THE DEPUTY COURT CLERK:** This is case number
4 16-MD-2700-TCK-TLW, In Re: Genentech Herceptin Marketing and
5 Sales Practices Litigation.

6 Counsel, please enter your appearance for the record.

7 **MR. KEGLOVITS:** From Gable, Gotwals on behalf of the
8 plaintiffs, we have Dave Keglovits, Steve Adams, Amy Fogleman,
9 Wes Pebsworth and Adam Doverspike. And with us in the
10 conference room is Cheryl Anderson, our senior paralegal.

11 **MR. SILL:** Good morning. Matthew Sill for plaintiffs.

12 **MR. O'CONNOR:** On behalf of Genentech, Bill O'Connor
13 and Alicia Donahue.

14 **MS. TABATABAIE:** Good morning. Tara Tabatabaie for
15 plaintiffs.

16 **MR. O'CONNOR:** And if you didn't get that, Camie, Gabe
17 Egli is with us, as well.

18 **THE DEPUTY COURT CLERK:** Thank you.

19 **THE COURT:** All right. Mr. Keglovits, after having
20 looked at the summary judgment briefing, what's your
21 perspective on your discovery?

22 **MR. KEGLOVITS:** Well, Judge, I think it leaves the
23 information we want largely unchanged. I think it does raise a
24 couple of additional areas of inquiry that we would want to
25 emphasize because of the emphasis on the impossibility of

1 actually changing the manufacturing process. But having looked
2 at it, I don't think it really modifies the scope of what we've
3 been discussing.

4 **THE COURT:** All right. Mr. O'Connor or Ms. Donahue,
5 what sort of progress have you made in terms of figuring out
6 what it would take to -- well, one, what is out there, and,
7 two, what it would take to gather the information and get it in
8 some sort of a searchable format?

9 **MS. DONAHUE:** So, just to back up one step, I wanted
10 to tell you, Your Honor, what we have produced since --
11 actually produced to the plaintiff since the last conference.
12 So we have produced to them 7,000 -- close to 8,000 more pages
13 of documents, including submissions to and correspondence with
14 the FDA regarding two labeling changes, one that occurred in
15 2000 and one that did not occur but was a label change
16 submission made at the request of the FDA in 2014.

17 We've also given them the CBEs, which are changes being
18 effected, labeling submissions that total about over 7,000
19 pages, and we've given them technical reports associated with
20 Genentech's investigation on a new drug application for
21 Herceptin.

22 So, they have, you know, they have a lot of new material to
23 review and we haven't heard from them, you know, what, if
24 anything, they think about that.

25 But in terms of what you asked us to do at the end of the

1 hearing, we have collected and loaded onto our vendors'
2 searchable platform the portion of the regulatory database that
3 we were talking about at the last hearing that is related to
4 Herceptin, and that is about 37,000-plus documents, 4.3 million
5 pages. And we have also loaded onto the same platform the
6 investigational new drug portion of the database, which is
7 another 68,000 pages, over 17,000 documents.

8 **THE COURT:** All right.

9 **MS. DONAHUE:** In terms of what it would take us to
10 review those documents that have been loaded for things like
11 privilege and responsiveness, we are estimating that that will
12 be close to 3,000 hours. There's a lot of information in the
13 documents that have been loaded that would have to be redacted.
14 There's things that are protected by HIPAA; there's proprietary
15 trade secret information. We would, you know, probably want to
16 meet and confer with the plaintiffs on search terms where we
17 would propose our search terms for them, and that would be the
18 logical next step in the process.

19 **THE COURT:** So, is what you have just summarized, does
20 that cover then all of the material the plaintiffs have
21 requested? And, again, I'm not getting to the issue of whether
22 or not it's got to be produced; I just want to make sure I've
23 got my hands around the scope of information that the
24 plaintiffs have requested and how much information there is and
25 what it would take to get all that information in a searchable

1 format. It sounds like you've put the information that you
2 just summarized in a searchable format, but is that the
3 universe of what the plaintiffs have been requesting?

4 **MS. DONAHUE:** No, it is not the universe of what
5 plaintiffs have been requesting.

6 The other items that we discussed at the last hearing
7 related to internal correspondence at Genentech, so -- and, you
8 know, our position remains that that is completely irrelevant
9 and in no way associated with our preemption motion.

10 We have taken steps to collect custodial files of the nine
11 employees that we have identified as having substantive
12 knowledge about the Herceptin approval process and other
13 categories the plaintiffs have identified in their discovery,
14 and we have -- so, you know, we've started to collect the
15 custodial files of those folks, imaged their laptops, and
16 collected e-mails, etc., but we have not loaded those onto the
17 same -- the platform that is -- where we have put the
18 regulatory database which is where, you know, where we believe
19 the -- I have additional information that the plaintiffs are --
20 that Your Honor ruled the plaintiffs are entitled to, that's
21 where it would be.

22 **THE COURT:** Okay. The way I view discovery, and I
23 think I've been trying to get this across but I think I'm just
24 not communicating very well, the way I view discovery is, you
25 know, one party asks for documents or serves interrogatories,

1 the other party responds with any legitimate objections to the
2 wording, and you work that out. And then I don't -- I
3 understand that there have been some objections to the wording,
4 but for the most part I think the plaintiffs' discovery
5 requests are relatively clear.

6 I haven't ruled at all yet on whether or not those
7 discovery requests are going to be -- are going to have to be
8 fully responded to because I don't know yet whether or not the
9 information they're seeking is going to have enough relevance
10 that it outweighs the costs.

11 So, setting all that aside, they served the discovery
12 requests, it's then the other parties' responsibility to come
13 back and say, "Okay, what you've requested is in bucket A, and
14 this is all of it, and this is what it would take in this sort
15 of a case to gather all of that." And I think I was pretty
16 clear last time that I don't want Genentech at this point to go
17 about the process of actually gathering it. I just want to
18 know and think the plaintiffs are entitled to know what is out
19 there and what would it take to gather it. And maybe I'm
20 misunderstanding. What I hear you saying is that you've
21 gathered a certain portion of responsive documents and already
22 put them into some sort of a searchable format and that there's
23 another set of documents that you would be in the process of
24 these custodial documents that you're ready to begin putting in
25 some sort of searchable format, but that you haven't engaged in

1 the effort to determine what's the full scope of information
2 requested by the plaintiffs and what would it take to gather
3 that information. Am I understanding that right?

4 **MS. DONAHUE:** No, Your Honor. We have made every
5 effort to search and find responsive documents and other
6 information responsive to their requests and we believe that
7 the vast majority of its responsive information is located in
8 the Herceptin-related regulatory database that we have loaded
9 onto our vendors' platform.

10 **THE COURT:** Okay. And then it sounds like you know
11 then what it would take to go gather the remainder? I mean, I
12 haven't asked you to gather it and I'm not suggesting that I'm
13 going to ask you to do that, but it sounds like then that you
14 do know what it would take to gather that information.

15 **MS. DONAHUE:** My understanding is that the remaining
16 information that we have not -- you know, that is not contained
17 in that regulatory database is the internal correspondence that
18 the plaintiffs seek and that's -- so that's, yes, you're
19 correct, that's where we are.

20 **THE COURT:** Okay. And then --

21 **MS. DONAHUE:** Yes, we have collected, imaged, and
22 started the process of collecting that, the internal
23 correspondence and custodial files for the individuals we have
24 identified in response to their discovery requests as having
25 substantive knowledge of the three categories that they've

1 requested. There are still some additional individuals. I
2 think we've identified 50 -- up to 50 individuals who may have
3 substantive knowledge, and we've determined that about half of
4 those are no longer with the company and we are still reviewing
5 additional folks to figure out just who knows what and, you
6 know, and what would be responsive to their request that
7 additional people may have information on.

8 But at this point, there's nine that we've identified to
9 them. I think we have two more that we can tell them would
10 have information responsive to their discovery requests and we
11 are working on collecting their files, as well.

12 **THE COURT:** Well, I mean, that certainly moves us down
13 the road a significant way. I mean, I had not asked you yet to
14 go through the process of actually gathering that information
15 because I didn't want to put Genentech to that cost and expense
16 unless I ruled that that information was actually going to be
17 producible, but it sounds like you've gone ahead and moved
18 forward with that.

19 So, here's how I would like to proceed at this point,
20 subject to me making sure that Judge Kern does not have an
21 objection. I want to stay the plaintiffs' response to the
22 dispositive motion. I want the parties to get together and
23 discuss what it would take to actually produce the information
24 that the plaintiffs have requested, and then I want a
25 submission from the parties jointly which would identify any

1 areas of dispute. Under each individual area of dispute, it
2 would then have a statement by the defendants of what it would
3 take to gather and produce that information. It would then
4 have a statement by the plaintiffs, and I hope these are brief
5 statements, as to why this information is relevant and needed
6 in order to respond to the summary judgment motion. It would
7 then have a statement by the defendants that would attempt to
8 rebut that. And then it would have a short reply by the
9 plaintiffs. However you all think and can jointly agree is the
10 best way to present that to me, I'm happy to take, take it in
11 that format, and I presume you all are capable of coming up
12 with some kind of format that would be as easy as possible for
13 me to review. At that point, I can then make a decision on
14 what is going to be produced. I would like the parties to take
15 into account Federal Rule of Evidence 502.

16 Ms. Donahue, absent a really strong argument, to the extent
17 that Genentech wants to individually review all these documents
18 for privilege or work product before searches are run that
19 would then create the documents that actually would be
20 produced, I will probably view that as a self-inflicted wound,
21 because I think the parties ought to take full advantage of
22 502, and certainly the defendants should in this case. Again,
23 I'll hear argument as to why you shouldn't have to do that, but
24 in the end in all likelihood, if Genentech is taking the
25 position that it's going to take -- I forget how many hours you

1 said, 3,000 hours -- to review each of these for privilege and
2 work product, you're going to have to have a really good reason
3 why you can't take advantage of 502 to eliminate a lot of that
4 time.

5 So, Mr. Keglovits, any comments, responses to my proposal?
6 And, of course, we'll set some deadlines here so that we keep
7 things moving along.

8 **MR. KEGLOVITS:** Your Honor, I think that is going to
9 be helpful in moving us toward a resolution. I do agree that
10 ultimately you're going to have to look at the discovery
11 responses because I think we still have a disagreement about
12 what should be within the scope of the search and I think this
13 vehicle will give you the chance to do that.

14 **THE COURT:** All right. Ms. Donahue, any comments,
15 responses about my proposal?

16 **MR. O'CONNOR:** Your Honor, Bill O'Connor.

17 I know you said you would implement some deadlines.
18 Obviously I think it's in the best interest of all parties, and
19 also consistent with Judge Kern's ruling, that this be set as
20 expeditiously as possible.

21 **THE COURT:** Okay. All right. Then when do you think
22 you all would have a chance to meet and make this submission?
23 Mr. Keglovits, I guess I'll hear from you first.

24 **MR. KEGLOVITS:** Okay. Well, Ms. Donahue began by
25 telling you they had produced the CBEs and technical reports,

1 and we did get those yesterday and we're working our way
2 through them.

3 I'm not sure what information they would like to give us to
4 review before we have this conversation. But whatever they
5 want to give us about the structure of the database, the
6 custodial files will be helpful to have in advance of that
7 conversation. I would think if they can get us that tomorrow,
8 we could probably plan a conversation midweek next week.

9 **THE COURT:** All right. Mr. O'Connor or Ms. Donahue?

10 **MS. DONAHUE:** I'm not sure what information we could
11 provide about the structure of our database that would be
12 helpful at this point. So I'm not sure that that's something
13 that -- I mean, it's a searchable platform, and right now, you
14 know, we don't have any kind of search terms agreed upon, so
15 other than that I don't know what more information I can
16 provide.

17 **THE COURT:** Well, what --

18 **MS. DONAHUE:** Our vendors' platform, we would have to
19 load it somewhere else. If the plaintiffs are going to access
20 it, we would, of course, prefer and it is usually the custom
21 and practice that we're familiar with that we would be doing
22 the searches and producing according to agreed search terms and
23 producing the documents to the plaintiffs. And understanding
24 Rule 502, we also have a lot of trade secret, patient privacy,
25 non-Herceptin related information in that regulatory database

1 that we would need to cull out and take care of before, you
2 know, just turning it over. So, that's about all I can tell
3 you about the structure of our vendors' database at this point,
4 but it's not the database that we -- a database that we would
5 allow plaintiffs access to, --

6 **THE COURT:** Well, I assume --

7 **MS. DONAHUE:** -- as long as we can transfer it
8 somewhere else once we agree on search terms and we've done our
9 review and redaction process.

10 **THE COURT:** I assume what Mr. Keglovits is asking is,
11 you know, by what the platform is, what -- you know, whose is
12 it. I mean, just to give a basic example, you know, is it
13 access, is it -- you know, what's the platform, what's the
14 search term -- or searching mechanism that it will support? Is
15 it strictly, you know, targeting single words or has it got
16 some terms and connectors abilities or has it got abilities
17 beyond that? I assume that's the sort of information that
18 Mr. Keglovits is asking for and it's certainly information that
19 I would think would be relevant.

20 I mean, we need to be transparent here in terms of, you
21 know, what documents are out there and the format or platform
22 that will be searched. The rest of it, whether or not the
23 searches are going to be conducted, whether or not this
24 information is going to be produced, you know, as I've said,
25 that's a decision for me to make here down the road. But in

1 terms of what's in it, what it's made up of, that sort of
2 thing, I think we need to be very transparent about that at
3 this point.

4 **MS. DONAHUE:** So, Your Honor, I'd be happy to have a
5 phone call with Mr. Keglovits tomorrow discussing, you know,
6 those kinds of issues --

7 **THE COURT:** Okay.

8 **MS. DONAHUE:** -- if that's what he feels like he needs
9 before we get to the more substantive issue of, you know, that
10 you've just identified and what you've asked us to do in terms
11 of the next -- the meet-and-confer.

12 **THE COURT:** All right. Well, do you all think you
13 could get this done and the submission to me within 30 days?

14 **MS. DONAHUE:** Yes.

15 **THE COURT:** Okay. Mr. Keglovits?

16 **MR. KEGLOVITS:** Your Honor, I do believe we can. I
17 just want to maybe suggest one other thing. We are talking
18 about the database itself, which I understand from the
19 discussion this morning had a targeted group of documents
20 placed into it. I think I'm understanding the court to say we
21 were trying to decide what it would take to produce the
22 information requested. As we go through our interrogatories
23 and requests for production, we're going to find some areas
24 where the information we want has not been -- was not in that
25 targeted group of documents and, thus, is not in the database,

1 and so I was anticipating we would also have a discussion with
2 them about what do they think it would take to go and get this
3 other information we want.

4 **THE COURT:** Yeah, that's exactly what I intend. And I
5 don't want, Ms. Donahue, Mr. O'Connor, I don't want you to
6 actually go get the information simply because the plaintiffs
7 have asked for it, but I do want part of the discussion to be
8 this is what will be required to get the information and this
9 is the format in which we believe we would then acquire it and
10 the means by which we would then have to search it and produce
11 it if the court orders that to take place. Now, it may not be
12 any of those areas. It may be that the full scope of
13 plaintiffs' requests have -- are in the process of being loaded
14 on or that Ms. Donahue or Mr. O'Connor knows exactly what it
15 would take. But if there is a category of documents that the
16 plaintiffs have requested, then that needs to be addressed in
17 terms of what it would take to go get those.

18 Does that make sense to --

19 **MS. DONAHUE:** I understand, Your Honor. We can and
20 will do what you've requested us to do and meet and confer with
21 the plaintiffs and do this submission within 30 days. Our
22 motions date is one that is important to us. You know, we
23 asked Judge Kern to have this motion heard early because we
24 believe it's dispositive and that the preemption issue is, you
25 know, completely dispositive of the case, so, you know, any

1 delay on being done with this is not something that we are, you
2 know, -- that we welcome, so we will expedite the meet-and-
3 confer and get you the submission that you've requested.

4 **THE COURT:** Okay. All right. Super. Then anything
5 else that we need to address this morning? Mr. O'Connor,
6 Ms. Donahue?

7 **MS. DONAHUE:** Not from our end.

8 **THE COURT:** All right. Mr. Keglovits?

9 **MR. KEGLOVITS:** Just a couple of things from me, Your
10 Honor.

11 In line with this theme of trying to get this thing
12 expedited, there is some third-party discovery we would like to
13 do via document subpoenas, and I know the court is taking a
14 very active role in managing the discovery here and I didn't
15 want to do something that would be counter to what the court
16 was hoping to accomplish. So I wanted to advise you that it's
17 our intention to serve those unless the court has some other
18 preference for how we proceed.

19 **THE COURT:** No, no. You should go ahead and serve
20 those. Obviously, I know you'll give notice immediately to
21 Mr. O'Connor and Ms. Donahue, and then if there's a basis for a
22 motion to quash, then, Ms. Donahue, Mr. O'Connor, any reason
23 you don't think you could get those motions on file within
24 seven days of receiving the subpoena?

25 **MR. O'CONNOR:** We can do that.

1 **THE COURT:** Okay. And then, Mr. Keglovits, when you
2 serve those subpoenas, if you receive notice from Mr. O'Connor
3 or Ms. Donahue that they are going to file a motion to quash,
4 if you could just notify the third parties that they shouldn't
5 actually produce any documents until there's been a ruling from
6 the court.

7 **MR. KEGLOVITS:** Sure.

8 **THE COURT:** Okay.

9 **MR. KEGLOVITS:** And one other thing I wanted to
10 mention, Your Honor. We had served a second set of discovery
11 requests pretty soon before the first hearing we had with Your
12 Honor, so it was not ripe, no answers had been given yet, it
13 was not ripe when we had the first hearing and so it wasn't
14 part of the motion to compel. We haven't filed a separate
15 motion to compel on those because we're wanting to let this
16 process work its way through. Can we include -- there's only,
17 I think, three or four discovery requests there that are
18 directed to a third-party manufacturing facility they have.
19 Can we include that in this joint submission we're going to
20 provide you?

21 **THE COURT:** Yes. Don't file a motion to compel;
22 include it in there and make sure that there's some indication
23 for me or to me that as to which ones fall into that category,
24 in other words, those for which a motion has not been filed.

25 **MR. KEGLOVITS:** Okay.

1 **MS. DONAHUE:** Your Honor, this is Alicia again. We
2 had one more issue relating to the always-recurring protective
3 order issue.

4 We had some e-mails back and forth with Mr. Keglovits about
5 the two people that, you know, he would identify on this
6 provision of the BLA that is so very sensitive, so they're
7 still thinking about which two of their client representatives
8 they're going to share it with. But we had had some
9 conversation and referenced by Your Honor at the last hearing
10 to kind of how it will work that they provide their client
11 representatives with the information, and we had anticipated
12 that it would be a situation where there were not copies made
13 or sent to these individuals, that the individuals would, you
14 know, meet with Mr. Keglovits and the other lawyers that he
15 wants them to meet with and review the documents, you know, in
16 a room, so the documents wouldn't be floating around out there
17 somewhere. You know, a little bit of a controlled environment.
18 But it sounds like that's not what Mr. Keglovits has in mind
19 based on e-mail -- the e-mail I just received from him this
20 morning. So, I mean, we can include that in the meet-and-
21 confer as well, but I just wanted to let you know that --

22 **THE COURT:** Yeah, I remember a discussion about that.
23 I think my suggestion would be not that they -- because I know
24 I originally suggested that, and I think Mr. Keglovits objected
25 to it, and I think after thinking about it my suggestion would

1 be that a hard copy can be given to these two individuals, but
2 that no copies should be made and electronic copies should not
3 be sent to them. It would be too easy for that to -- a mistake
4 to be made and for that to get forwarded to somebody or get
5 placed somewhere other people could see it. But I don't have
6 any problem with an actual hard copy that has very clearly
7 labeled on every page, you know, that it's not to be copied
8 provided to those two individuals.

9 **MS. DONAHUE:** All right. That's acceptable. Thank
10 you.

11 **THE COURT:** Mr. Keglovits, will that work for you?

12 **MR. KEGLOVITS:** Sure.

13 **THE COURT:** Okay. All right. Then --

14 **MS. DONAHUE:** One hard copy made; right?

15 **THE COURT:** Yeah, for each -- one hard copy for each
16 of the two individuals. They'll each have their own copy.

17 **MS. DONAHUE:** Okay. Thank you.

18 **THE COURT:** All right. So, Ms. Donahue, Mr. O'Connor,
19 anything else?

20 **MR. O'CONNOR:** Nothing here.

21 **THE COURT:** Mr. Keglovits, anything else?

22 **MR. KEGLOVITS:** Just to kind of put a bow on all of
23 this, is it Your Honor's intention to have a communication with
24 Judge Kern's chambers so we'll know shortly whether we do have
25 a stay on the response date, or do we need to do an application

In Re: Genentech Herceptin (08-26-2016 Discovery Conference)

20

1 for that?

2 **THE COURT:** No; I will enter a minute order by Monday
3 that either stays that deadline or sets a very quick telephone
4 conference so we can all figure out how we're going to deal
5 with his decision not to stay it.

6 **MR. KEGLOVITS:** Thank you, Your Honor.

7 **THE COURT:** One or the two.

8 All right. Well, I hope everybody has a nice weekend. I
9 appreciate your time and I'm sure we'll be visiting shortly.
10 Thank you.

11 **MS. DONAHUE:** Thank you.

12 **MR. KEGLOVITS:** Thanks.

13 (PROCEEDINGS CLOSED)

14 **REPORTER'S CERTIFICATION**

15 WHILE NOT PRESENT IN PERSON TO STENOGRAPHICALLY REPORT THE
16 FOREGOING PROCEEDINGS, I CERTIFY THAT IT WAS TRANSCRIBED TO THE
17 BEST OF MY ABILITY FROM A DIGITAL AUDIO RECORDING.

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